JAN 3 1 2006

K053177

SECTION D. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, this 510(k) Summary is provided:

Submitter: Medtronic MiniMed, 18000 Devonshire St., Northridge, CA 91325

Contact: Staci Ellis (818) 576-5959

Name of Device: Medtronic MiniMed Paradigm Model MMT-712E Insulin Pump

Predicate Device: Medtronic MiniMed Paradigm Model MMT-712 Insulin Pump

Description of the Device: The Paradigm Model MMT-712E is an external, portable insulin pump, designed for continuous delivery of insulin. It is designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per meal bolus. The insulin programming step size allows users to program insulin delivery in steps of 0.1 units for boluses and 0.05 units/hour for basal delivery.

The Model 712E accommodates a proprietary 3.0 ml reservoir. This reservoir mates with the existing and future Paradigm infusion sets.

Intended Use of the Device: The Medtronic MiniMed Paradigm Model 712E Insulin Pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Comparison of the Technological Features of the New Device and Predicate Device: The new and predicate devices have identical materials and design. The new device, MMT-712E, is a derivative of the MMT-712. Both pumps are mechanically identical. Software modifications only were made to the MMT-712E to disable certain features, thereby simplifying its use.

Mark Faillace
Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed

11/10/05
Date

™ Paradigm Model 712E insulin pump is a Trademark of Medtronic MiniMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Ms. Staci Ellis
Senior Regulatory Affairs Specialist
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325

Re: K053177
Trade/Device Name: Medtronic MiniMed Paradigm Model MMT-712E Insulin Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: November 14, 2005
Received: November 15, 2005

Dear Ms. Ellis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053177

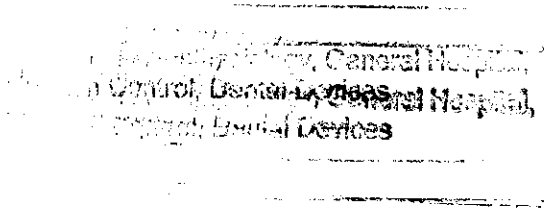
Device Name: Medtronic MiniMed Paradigm Model MMT-712E Insulin Pump

Indications For Use: The Medtronic MiniMed Paradigm Model 712E Insulin Pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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